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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,734	01/25/2002	A. Robert Spitzer	0594.00034	9911

7590 09/09/2003

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EXAMINER	
BERKO, RETFORD O	
ART UNIT	**PAPER NUMBER**
1615	7

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/056,734	SPITZER, A. ROBERT	
	Examiner	Art Unit	
	Retford Berko	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *1-21,28,29,31 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-27 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Acknowledgement of papers received: Applicant's provisional election without traverse, of species III, which is directed to claims 22-27 and 30, in Paper No. 6 is acknowledged.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

a. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention in that the claim referes to "valproate salts and valproate variations thereof", making it unclear as to the metes and bounds of the invention. Also, Claim 23 is rejected under Sec. 112 second paragraph because the use of the term "valproate variations" lacks antecedent basis. Applicant may overcome the rejection by clarifying what valproate variations means.

b. In regards to claim 24, the phrase "ergotamine-like agents" renders the claim indefinite because it is an improper Markush group and it is unclear what specific compounds fall into the group. Applicant may overcome the rejection by naming specific compound in the group.

c. In regards to Claim 24, the term "5HT agonists" renders the claim indefinite because 5HT is not readily discernable or understood in the art. Applicant may overcome the rejection by specifying what biochemical entity or what activity is regulated by the compounds referred to as "agonists" in the claim.

2. Claim 30 is rejected under 35 U.S.C. Sec 112, first paragraph, because the specification, while being enabling for the administration of effective amount of the valproate and its salts as suppository, does not reasonably provide enablement for the use of any medicament composition into the rectum of an individual for treating migraine headache. The specification does not

enable any person skilled in the art, to which it pertains, or with which it is most nearly connected, to use all medicaments in the form as suppository to treat migraines as commensurate in scope of the claim.

Claim Rejections-Sec. 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 22-25, 27 and 30 are rejected under 35 U.S.C. 102 (b) as anticipated by prior art taught by Baker et al (US 6, 071, 927) and by Crocker et al (US6, 096, 742). Applicant's claims are drawn to a suppository composition including valproate, aspirin, naproxen, acetaminophen, ibuprofen, serotonin agonists, thickners, solvents and preservatives for treatment of migraines.

3. Baker et al taught an invention that treatment or prevention of pain, inflammation, migraine and emesis could be achieved by rectal administration of a composition comprising effective amounts of acetaminophen, aspirin, ibuprofen and naproxen and valproate (abstract, col 8, lin 48, col 14, lin 15-25 and col. 21, lin 30-35). *Thus, applicant's invention in Claims 22-25 and 27 and 30 was taught by the invention patented by Baker et al. Therefore,* applicant is precluded from obtaining a patent for invention described in claims 22-25, 27 and 30; consistent with the requirements of Sec.102(b).

4. Crocker et al taught an invention wherein headache, migraine and pain were treated by administration of a composition comprising acetaminophen, aspirin, ibuprofen, naproxen and valproate (col 10, lin 65; col 12, lin 50-55). The reference also teaches that the composition may

be used in the form of a pharmaceutical preparation in solid, semisolid or liquid form; that the active ingredient may be compounded with pharmaceutically acceptable carriers for tablets, capsules and suppositories in addition, auxiliary thickening and coloring agents. Furthermore, the prior art taught that isopropyl acetate was used as the solvent (col 14, lin 31-50). The teachings in Crocker et al are implicit to a person skilled in the art to invent a composition as claimed by applicant because the composition as a suppository will constitute an effective delivery of the medication for treatment of migraine as taught by the prior art. Therefore, applicant is precluded from obtaining a patent for the invention described in claims 22-25, 27 and 30; consistent with Sec. 102(a).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. Sec. 103(a) are summarized as follows:

a. Determining the scope and contents of the prior art
b. Ascertaining the differences between the prior art and the claims at issue.
c. Resolving the level of ordinary skill in the pertinent art.
d. Considering objective evidence present in the application indicating obviousness or nonobviousness

6. Claim 26 is rejected under 35 U.S.C. Sec. 103(a) as obvious over Curtis et al (US 6, 071, 923). Claim 26 is directed to the dosages of 750 mg, 100 mg and 1500 mg as the suppository composition. Curtis et al teach that a composition for treatment of migraine was used in

conjunction with other anti-migraine agents ergotamines, acetaminophen, naproxen and valproate (col 14, lin 45-65 and abstract and col 22, lin 2).

7. Claim 26 differs from the teaching in Curtis et al by reciting various doses of the composition. Where the general conditions of a claim are disclosed in the prior art it is not inventive to discover the optimum or workable ranges by routine experimentation. See In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955). The preparation of various compositions having various amounts of the active ingredient is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. In re Russel, 439 F.2d 1228, 169 USPQ 426 (CCPA 1971).

Correspondence

Any inquiry concerning this communication or earlier communications should be directed to Retford Berko whose telephone number is 703-305-4442. The examiner can normally be reached on M-F from 8:00 a.m.-5:00 p.m.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached at 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648. An inquiry of general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

THURMAN K. PAGE, J.D.
SUPERVISORY PATENT EXAMINER